## PSJ3 Exhibit 473

To: Gil Genn[gil.genn@capitolhillstrategicadvocates.com]

**Cc:** Sisson, Karen[karen.sisson@walgreens.com]; Jill McCormack[JMcCormack@NACDS.org];

Diane Darvey[ddarvey@NACDS.org]

From: Janet M Hart

**Sent:** 2014-03-31T18:42:42-04:00

Importance: Normal

Subject: Re: MD Wholesaler bill TPs

**Received:** 2014-03-31T18:42:42-04:00

I don't think so... I would try to kill... Have to have definition of intra company etc

Sent from my iPhone

On Mar 31, 2014, at 6:21 PM, "Gil Genn" < gil.genn@capitolhillstrategicadvocates.com> wrote:

## Karen:

I hope Janet chimes in. Intra-company would get to the issue of us notifying our own stores?

I won't say much then other than agree with HDMA and this conflicts with the CFR and we will have to notify our own stores.

Gil

From: Sisson, Karen [mailto:karen.sisson@walgreens.com]

Sent: Monday, March 31, 2014 5:52 PM

To: Jill McCormack

**Cc:** Gil Genn; Janet M Hart; Diane Darvey **Subject:** Re: MD Wholesaler bill TPs

I agree Jill.

Karen A. Sisson, Esq.
State Government Relations
Walgreen Co.
(224) 723-2633 (cell)
On Mar 31, 2014, at 4:49 PM, "Jill McCormack" < JMcCormack@NACDS.org> wrote:

I was under the impression we wanted to help our business partners HDMA kill this bill. If we start asking for amendments do we run the risk that the bill is improved and then passes? I understand we need to protect our own butts in the end, but should we be primarily trying to kill it?

Jill McCormack | Regional Director, State Government Affairs National Association of Chain Drug Stores 1502 Capitol View Drive | New Cumberland, PA 17070 717.525.8962 (office) 717.592.8977 (cell) 717.303.3455 (fax)

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From: Gil Genn [mailto:gil.genn@capitolhillstrategicadvocates.com]

Sent: Monday, March 31, 2014 5:28 PM

To: 'Janet M Hart'

Cc: 'Karen Sisson'; Jill McCormack; Diane Darvey

Subject: RE: MD Wholesaler bill TPs

## Janet:

Diane facilitated a call with Dan Bellingham. Basically, Dan said he was going to go with his testimony from last time and he is going to be very short and say MD will be the first in the nation to do this and turn it over to John Gilbert, former DEA to discuss. I said I'd go with our points. There was a little pushback on our proposed amendment for CDS. However, it was suggested by Diane that maybe we just exempt intra-company transfers and that takes care of our issue.

Please advise.

Gil

From: Janet M Hart [mailto:jhart@riteaid.com]

Sent: Monday, March 31, 2014 4:57 PM

To: Gil Genn

Cc: Karen Sisson; Jill McCormack; Diane Darvey

Subject: RE: MD Wholesaler bill TPs

Gil

Good points...what did HDMA state?

From: Gil Genn [mailto:gil.qenn@capitolhillstrategicadvocates.com]

**Sent:** Monday, March 31, 2014 10:43 AM

To: Janet M Hart

Cc: Karen Sisson; Jill McCormack; Diane Darvey

Subject: FW: MD Wholesaler bill TPs

## Janet:

Per the call here's what I've learned so far:

- We object because this conflicts with CSA and the CFR indicating that the wholesaler must have notice. (I need to see the CFR language). The Wholesaler is required to give notice to the DEA when an extraordinary order for Hydrocodone, e.g., is made out of line from past ordering patters by a pharmacy.
- This would force us (Rite Aid and Walgreen's at least) to notify our own stores of any shortage. The stores don't need notice, they can log onto inventory control and see the status and when the next expected shipment is. This is unnecessarily duplicative, burdensome and STUPID (IoI).
- We can offer an amendment that says this section 'shall not apply to controlled dangerous substances.' (Need to vet with HDMA, because it may make the bill more palatable to pass, but gut the intent of the Independents).

Let me know what else.

I made comments/questions below in red to Diane's compilation of HDMA

testimony. Any addition insight is welcome! Thanks, Gil

From: Gil Genn [mailto:qil.genn@capitolhillstrategicadvocates.com]

Sent: Monday, March 31, 2014 9:15 AM

**To:** Diane Darvey **Cc:** Jill McCormack

Subject: FW: MD Wholesaler bill TPs

Diane:

My comments in red:

We are concerned that House Bill 596 will have major unintended consequences by placing unworkable unnecessary requirements on wholesale drug distributors with the potential to disrupt the drug distribution supply chain.

We cannot support matters that would potentially result in unnecessary and unworkable restrictions on the drug distribution supply chain.

We have concerns with the 30-day advance notification provision before the wholesale drug distributor before imposing any purchase limits on a pharmacy, and required weekly updates on the quantity available to the pharmacy.

- With the many hundreds of thousands of drug products distributed in the supply chain, we are concerned that these requirements would cause disruptions by diverting wholesale drug distributors from supply medications and instead spending their time with endless counts and notifications, that could easily be out of date shortly.
- The drug distribution supply chain is very busy with drug products coming in to a wholesaler and going out quickly to supply drugs to pharmacies. It would also be of little use as drug product shortages and manufacturer supplies are not usually foreseeable or predictable.
- ☐ Frankly, we question how it would even be

possible to do what this legislation is asking.

- Because product shortages are typically impossible to predict, absent a crystal ball, we struggle to see the feasibility of what is being proposed. THIS SOUNDS LIKE BS TO ME, IF DRUG X IS A COMPONENT OF A LARGER DRUG, VACCINE ETC AND YOU KNOW THE DRUG COMPONENT CANT BE SECURED ON X DATE, THEN YOU CAN PREDICT UPCOMCING SHORTAGE. IM NOT GOING TO SAY THINGS UNLESS VERIFIED.
- Moreover, pharmacies already get notices from wholesalers when drugs are recalled or drug shortages are occurring and the Food and Drug Administration provides information to the supply chain. ARE THEY TIMELY? HOW SOON?

In addition, we have concerns that this would directly conflict with regulatory requirements for that wholesalers and pharmacies must comply with relative to drug diversion and suspicious orders for controlled substances.

- □ The federal Controlled Substance Act (CSA) the federal law that governs the prescribing,
  distribution and dispensing of controlled
  substances requires controls to guard against
  theft and diversion of controlled substances and
  systems to check for suspicious orders of
  controlled substances." HOW DOES IT WORK
  AND WHAT ARE THE 'CONTROLS'?
- □ We have concerns that this bill could conflict with those requirements and give bad actors an unfair advantage.

HOW WOULD IT GIVE BAD ACTORS AN ADVANTAGE?

Thank you again for this opportunity to provide testimony.

From: Jill McCormack [mailto:JMcCormack@NACDS.org]

Sent: Sunday, March 30, 2014 10:31 PM

To: Gil Genn

Subject: FW: MD Wholesaler bill TPs

See below . . .

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From: Diane Darvey

Sent: Friday, March 28, 2014 3:54 PM

To: Jill McCormack

**Subject:** MD Wholesaler bill TPs

Sure, here are some paragraphs for Gil to use as TALKING POINTS to give oral testimony.

As we are not wholesalers and this is a wholesaler bill, and outside of our issues, I have not drafted written testimony.

Gil can turn this into written testimony if he needs to.

Good morning, I am Gil Genn,

Thank you for the opportunity to provide testimony today regarding HB 596.

We are concerned that House Bill 596 will have major unintended consequences by placing unworkable unnecessary requirements on wholesale drug distributors with the potential to disrupt the drug distribution supply chain.

We cannot support matters that would potentially result in unnecessary and unworkable restrictions on the drug distribution supply chain.

We have concerns with the 30-day advance notification provision before the wholesale drug distributor before imposing any purchase limits on a pharmacy, and required weekly updates on the quantity available to the pharmacy.

- □ With the many hundreds of thousands of drug products distributed in the supply chain, we are concerned that these requirements would cause disruptions by diverting wholesale drug distributors from supply medications and instead spending their time with endless counts and notifications, that could easily be out of date shortly.
- ☐ The drug distribution supply chain is very busy with drug products coming in to a wholesaler and going out quickly to supply drugs to pharmacies. It would also be of little use as drug product shortages and manufacturer supplies are not usually foreseeable or predictable.
- ☐ Frankly, we question how it would even be possible to do what this legislation is asking.
- Because product shortages are typically impossible to predict, absent a crystal ball, we struggle to see the feasibility of what is being proposed.
- Moreover, pharmacies already get notices from wholesalers when drugs are recalled or drug shortages are occurring and the Food and Drug

Administration provides information to the supply chain.

In addition, we have concerns that this would directly conflict with regulatory requirements for that wholesalers and pharmacies must comply with relative to drug diversion and suspicious orders for controlled substances.

- The federal Controlled Substance Act (CSA) the federal law that governs the prescribing, distribution and dispensing of controlled substances requires controls to guard against theft and diversion of controlled substances and systems to check for suspicious orders of controlled substances."
- ☐ We have concerns that this bill could conflict with those requirements and give bad actors an unfair advantage.

Thank you again for this opportunity to provide testimony.

From: Jill McCormack

Sent: Friday, March 28, 2014 1:08 PM

To: Diane Darvey

**Subject:** did you see my note about teh wholesalers bill in MD?

Gill needs BRIEF testimony to present on Tuesday. It's been scheduled for committee. HB 596. Can you put together and put on NACDS letterhead?

Thanks!

Jill McCormack | Regional Director, State Government Affairs

**National Association of Chain Drug Stores** 

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